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A1

WO 01/17496 (54) Title: SKIN-BALANCE MOISTURIZING CREAM

(57) Abstract: The invention relates to an oil-free skin care composition for moisturizing the skin comprising (a) a humectant comprising glycerin and propylene glycol; (b) an emollient comprising isohexadecane, cyclomethicone, dimethicone, dimethicone copolyol and trimethyl siloxysilicate; (c) a keratolytic agent; and (d) water. The skin care compositions according to the invention accomplish effective moisturization through a combination of the softening effects of emollients with the moisture retaining action of humectants and coating activities of lubricants. The combination of ingredients counteract the effect of moisture loss, thereby keeping skin soft, smooth and supple. The compositions according to the invention are non-comedogenic and have long lasting moisturizing effects without the use of occlusive materials.

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## SKIN-BALANCE MOISTURIZING CREAM

This application claims priority to U.S. provisional application serial no. 60/153,005 filed September 9, 1999, the disclosure of which is hereby incorporated by reference.

### 5 FIELD OF THE INVENTION

The invention relates to a non-comedogenic skin care composition that effectively moisturizes the skin through a combination of the softening effects of emollients with the moisture retaining action of humectants and coating activities of lubricants, to counteract the effect of moisture loss, thereby keeping skin soft, smooth  
10 and supple.

### BACKGROUND OF THE INVENTION

It is known that skin protection and a long lasting moisturizing effect is best achieved through water-in-oil emulsions. See, for example, U.S. Patent No. 3,818,105.  
15 However, such emulsions compromise aesthetics due to their oily and greasy after feel when applied to the skin. Certain water-based products, *i.e.*, oil-in-water emulsions, are oil-free and non-greasy but lack sufficient moisturizing properties. U.S. Patent No. 4,389,419 discloses a skin care water-out emulsion composition to moisturize and condition the skin comprising mixture of petrolatum or mineral oil, a quaternary  
20 ammonium emulsifier, a fatty alcohol and a fatty ester emollient. While this composition counteracts the effect of moisture loss, thereby keeping the skin soft, smooth and supple, the presence of petrolatum and mineral oils makes the composition difficult to emulsify as well as render it cosmetically unacceptable.

The problems associated with an effective skin moisturizing product are even  
25 more profound in the teenage market where the mode of moisturizing is seen as conflicting with keeping skin free of pimples and comedones. Teenagers normally avoid moisturizers because they are perceived to worsen problematic skin. However, adequate hydration is necessary for healing and to reduce dryness, thereby, maintaining the integrity of the skin's barrier function.

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Accordingly, there remains a need for an effective skin moisturizing composition that is effective at moisturizing the skin without the leaving an oily or greasy feel to the skin and is non-comedogenic.

It has surprisingly been discovered that a light, oil-free, non-greasy, water based 5 cream emulsion, that is easy to spread, quick absorbing, long lasting, and non-comedogenic can be obtained through a specific combination of emollients, humectants and keratolytic agent.

### **SUMMARY OF INVENTION**

10 Accordingly, the invention relates to an oil-free skin care composition for moisturizing the skin comprising:

- (a) a humectant comprising glycerin and propylene glycol;
- (b) an emollient comprising isohexadecane, cylcomethicone, 15 dimethicone, dimethicone copolyol and trimethylsiloxysilicate;
- (c) a keratolytic agent; and
- (d) water.

The skin care compositions according to the invention accomplish effective 20 moisturization through a combination of the softening effects of emollients with the moisture retaining action of humectants and coating activities of lubricants. The combination of ingredients counteract the effect of moisture loss, thereby keeping skin soft, smooth and supple. The compositions according to the invention are non-comedogenic and have long lasting moisturizing effects without the use of occlusive materials.

### **DETAILED DESCRIPTION**

25 The invention relates to a skin care composition for moisturizing the skin comprising a humectant, an emollient, a keratolytic agent and water. The skin care composition according to the invention is an oil-free, water-based, *i.e.*, oil-in-water emulsion. In the context of the invention, the phrase "oil-free" means free from 30 petrolatum or any ingredient with the name "oil" in its nomenclature, including, for example, mineral oil.

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The skin care compositions according to the invention comprise at least one humectant which increases the water content of the top layer of the skin by actively attracting and retaining the moisture where it is needed to relieve dry skin. The skin's moisture level is thereby increased without feeling heavy and occlusive.

5 The humectant is preferably present in an amount of from about 2 to about 10 wt. %, based on the total composition. Suitable humectants for use in the present invention include glycerin, propylene glycol, and mixtures thereof. In a particularly preferred embodiment, the humectant is a mixture of from about 1 to about 5 wt.% of glycerin and from about 1 to about 5 wt. % of propylene glycol, even more preferably, from about 2  
10 to about 3 wt. % glycerin and from about 2 to about 3 wt. % propylene glycol, based on the total composition.

The skin care composition according to the invention also contain an emollient. The emollient useful in the skin care composition according to the invention contains a mixture of isohexadecane, cyclomethicone, dimethicone, dimethicone copolyol, and  
15 trimethylsiloxysilicate. The emollients act indirectly to soften the stratum corneum by slowing down the loss of moisture to the environment, allowing the skin to re-moisturize itself from within.

The dimethicone and trimethylsiloxysilicate offers skin protection and long lasting lubricity with a light touch and do not interfere with the skin's transpiration. The  
20 combination of cyclomethicone and dimethicone copolyol is normally used for preparing water-in-cyclomethicone emulsions. In the skin care compositions according to the invention, the cylcomethicone and dimethicone copolyol is used as a delivery system for the emollients. Being a water-based emulsion, *i.e.*, oil-in-water, once applied to the skin, the volatile components evaporate, imparting a cooling effect on the skin as well as  
25 leaving behind the heavier, more effective skin conditioning agents on the skin.

In addition to providing emolliency, the dimethicone copolyol is a silicone glycol copolymer that provides humectant benefits in addition to emolliency. Examples of commercially available dimethicone copolyols useful herein sold by Dow Corning Corporation are DC 190, DC 193, DC Q2-5220, DC 2501 Wax, DC 2-5324 fluid, and

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DC 3225C (this later material being sold as a mixture with cyclomethicone). Cetyl dimethicone copolyol is commercially available as a mixture with polyglyceryl-4 isostearate (and) hexyl laurate and is sold under the tradename ABIL.RTM. WE-09 (available from Goldschmidt).

5        Trimethylsiloxysilicate is a polymeric material corresponding to the general chemical formula  $[(\text{CH}_2)_3 \text{SiO}_{1/2}]_x [\text{SiO}_2]_y$ , wherein x is an integer from about 1 to about 500 and y is an integer from about 1 to about 500. A preferred commercially available trimethylsiloxysilicate is sold by Dow Corning as a mixture with dimethicone as DC 593.

10      Suitable dimethicones useful as an emollient in the skin care composition of the invention are commercially available from Dow Corning as the Dow Corning 200 series. A particularly preferred dimethicone for use in the skin care compositions of the invention is available from Dow Corning is DC200/350cst.

15      In a preferred embodiment, the skin care composition according to the invention comprises from about 3 to about 15 wt.% of the emollient. Particularly preferred is a combination of from about 1.0 to about 4.0 wt.% isohexadecane, from about 1.0 to about 5.0 wt.% of DC 3225C, and from about 0.5 to about 3.0 wt.% of DC 593 and from about 0.5 to about 3.0 DC 200/350 wt.% cst based on the total weight of the composition.

20      The keratolytic agent useful in the skin care compositions according to the invention should be effective in preventing pimples and comedones. Suitable keratolytic agents include alpha hydroxy acids and beta hydroxy acids. The most preferred keratolytic agent is salicylic acid. Preferably, the keratolytic agent is present in the skin care compositions according to the invention at from about 0.25 to about 2.0 wt.%, more preferably from about 0.5 to about 2.0 wt.%, based on the total composition.

25      The skin care composition according to the invention preferably contains an effective stabilizing amount of an emulsifier. Preferably, the emulsifier is present at from about 1.0 to about 10.0, more preferably from about 3.0 to about 6.0, weight percent, based on the total composition. Any emulsifier that is compatible with the 30 components of the composition can be employed. However, it has been discovered that when stearic acid is the primary emulsifier, it also helps provide the skin feel of the

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product. Additionally, when used as co-emulsifiers, cetyl alcohol and stearyl alcohol also provide lubricating properties for the skin. Accordingly, in a preferred embodiment, the emulsifier used in the skin care composition of the invention is a mixture of from about 0.5 to about 3.0, more preferably from about 1 to about 2, weight percent, based 5 on the total composition, each of stearic acid, cetyl alcohol and stearyl alcohol.

The emulsion can be further stabilized by inclusion of a small quantity of a thickener. The thickener is used in amount of about 0.01 to about 10% by weight based upon the weight of the coating composition. The range of about 0.01 to about 5% by weight is preferred, with the range of about 0.03 to about 1.0% by weight being 10 particularly preferred. The thickener can be a non-associative thickener or stabilizer, such as a homopolymer or a copolymer of an olefinically unsaturated carboxylic acid or anhydride monomers containing at least one activated carbon to carbon olefinic double bond and at least one carboxyl group or an alkali soluble acrylic emulsion.

Alternatively, an associative thickener or stabilizer can be used, such as a 15 hydrophobically modified alkali soluble acrylic emulsion or a hydrophobically modified nonionic polyol polymer, *i.e.*, a hydrophobically modified urethane polymer, or combinations thereof. The copolymers are preferably copolymers of a polycarboxylic acid monomer and a hydrophobic monomer. The preferred carboxylic acid is acrylic acid. The homopolymers and copolymers preferably are crosslinked.

20 Homopolymers of polyacrylic acid are described, for example, in U.S. Pat. No. 2,798,053, the disclosure of which is hereby incorporated by reference. Examples of homopolymers which are useful include Carbopol Registered TM 934, 940, 941, Ultrez 10, ETD 2050, and 974P polymers, which are available from The B. F. Goodrich Company. Such polymers are homopolymers of unsaturated, polymerizable carboxylic 25 monomers such as acrylic acid, methacrylic acid, maleic acid, itaconic acid, maleic anhydride, and the like.

Hydrophobically modified polyacrylic acid polymers are described, for 30 example, in U.S. Pat. Nos. and 5,349,030, the disclosures of which are herein incorporated by reference. These polymers have a large water-loving hydrophilic portion (the polyacrylic acid portion) and a smaller oil-loving hydrophobic portion (which can be derived from a long carbon chain acrylate ester). Representative higher

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alkyl acrylic esters are decycl acrylate, lauryl acrylate, stearyl acrylate, behenyl acrylate and melissyl acrylate, and the corresponding methacrylates. It should be understood that more than one carboxylic monomer and more than one acrylate ester or vinyl ester or ether or styrenic can be used in the monomer charge. The polymers can be dispersed in 5 water and neutralized with base to thicken the aqueous composition, form a gel, or emulsify or suspend a deliverable. Useful polymers are sold as Carbopol Registered TM 1342 and 1382 and Pemulen Registered TM TR-1, TR-2, 1621, and 1622, all available from BFGoodrich. Particularly preferred is Pemulen TR-1 (CTFA Designation: Acrylates/10-30 Alkyl Acrylate Crosspolymer).

10 Neutralizing agents suitable for use in neutralizing acidic group containing hydrophilic gelling agents herein include sodium hydroxide, potassium hydroxide, ammonium hydroxide, monoethanolamine, diethanolamine and triethanolamine.

15 The skin care compositions according to the invention preferably has a pH which provides a suitable environment for the keratolytic agent efficacy as well as to maintain the skin's moisture balance where the pH is in the range of 4.5 to 6.5. Preferably, the pH of the composition ranges from 5.5 to 6.5.

Generally, the water content of the skin care compositions according to the invention ranges from about 75 to about 85 wt.%, preferably from about 75 to about 80 wt.% water. This relatively high water content makes the cream light and easy to apply. 20 The compositions are preferably formulated so as to have a product viscosity of from about 75,000 to about 300,000 cps.

The skin care compositions according to the invention can comprise additional ingredients commonly found in skin care compositions, such as for example, preservatives, antioxidants, perfumes, chelating agents, etc., provided that they are 25 physically and chemically compatible with the other components of the composition.

Examples of suitable preservatives for use in the skin care compositions of the invention include the C<sub>1</sub>-C<sub>4</sub> alkyl parabens and phenoxyethanol. Generally, the preservative is present in an amount ranging from about 0.5 to about 2.0, preferably about 1.0 to about 1.5, weight percent based on the total composition. In a preferred embodiment, the 30 preservative is mixture of from about 0.2 to about 0.5 weight percent methylparaben, from about 0.2 to about 5.0 weight percent propylparaben and from about 0.05 to about

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0.10 weight percent butylparaben. A particularly preferred commercially available preservative that may be used in the skin care composition according to this invention is PHENONIP TM which is a practically colorless, viscous, liquid mixture of phenoxyethanol, methylparaben, ethylparaben, propylparaben, and butylparaben  
5 available from Nipa Laboratories, Inc., Wilmington, Del.

Preferably, an oil-soluble antioxidant should be present in the skin care compositions according to the invention. Suitable antioxidants include butylated hydroxy toluene (BHT), ascorbyl palmitate, butylated hydroanisole (BHA), phenyl- $\alpha$ -naphthylamine, hydroquinone, propyl gallate, nordihydroquiaretic acid, and mixtures  
10 thereof. Preferably the antioxidant is BHT and is present in the composition at from about .02 to about .05wt%, most preferably from about .02 to about 0.10.

Fragrances suitable for use in the skin care compositions according to the invention are well known in the art. Particularly preferred are those that can provide a fruity and/or floral fragrance, such as, for example, Mod Twist, commercially available from Haarmann  
15 & Reimer Corp.

In certain aspects of this invention, the compositions should include a chelating agent. Chelating agents which are useful in the compositions of the present invention include ethylenediamine tetra acetic acid (EDTA) and derivatives and salts thereof, dihydroxyethyl glycine, citric acid, tartaric acid, and mixtures thereof. The chelating  
20 agents should be utilized in a stabilizing effective amount and may range from about 0.01 to about 2% based on the weight of the total composition, preferably from about 0.05 to about 1%. Most preferably, the chelating agent should be EDTA.

Other ingredients may include agents which assist in protecting the skin from aging, such as sunscreens, anti-oxidant vitamins such as ascorbic acid, vitamin B, biotin,  
25 pantothenic acid, vitamin D, vitamin E and vitamin C, and sodium bisulfite. Yeast extract, gingko biloba, bisabolol, panthenol, alpha hydroxy acids and oligosaccharides such as melibiose are among other ingredients which assist in preventing aging of the skin by such means as irritation mitigation, oxidation mitigation, healing, affecting retinoid metabolism and inhibiting the production of elastase.

30 Ingredients with a low comedogenicity capacity should be chosen in order to render the product non-comedogenic.

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The skin care compositions according to the invention accomplish effective moisturization through a combination of the softening effects of emollients with the moisture retaining action of humectants and coating activities of lubricants, to counteract the effect of moisture loss, thereby keeping skin soft, smooth and supple. The 5 compositions according to the invention have long lasting moisturizing effects without the use of occlusive materials.

The compositions of the present invention can be prepared by well-known mixing or blending procedures. Each phase of the emulsion is preferably separately prepared with all of the components contained in the appropriate phase, except that it is 10 usually preferred to omit the retinoid compound initially. The emulsion is then formed normally by adding the oil phase to the water phase with agitation, and the emulsion should be cooled down when the retinoid compound is added. Set forth below is an example of a preferred method for preparing the skin care composition according to the invention.

15

**Salicylic Acid (premix 1):**

In a separate vessel, salicylic acid is added to propylene glycol and mixed until clear

20 **Phase A (main batch)**

1. Purified water is added to mixing vessel.
2. Start side sweep scraper and agitator.
3. EDTA is added and mixed until dispersed.
4. Pemulen TR-1 is sprinkled in and mixed well until dispersed.
5. The composition is heated to 70-75°C whilst mixing. At 70-75°C, Carbopol ultrez 10 is sprinkled in and mixed until dispersed.
6. At 70-75°C, methylparaben is added and mixing is continued.
7. Glycerin is added and mixing continued.

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8. The composition is held at 70-75°C for phasing.

**Phase B (oil phase)**

9. Isohexadecane is added to a separate vessel  
5 followed by cetyl alcohol and heated to 75-80°C, to allow all  
ingredients to melt.

10. At approximately 55-65°C, propylparaben is added  
followed by butylparaben with mixing after each addition until  
well dispersed

11. Butylated hydroxy toluene is added and mixed.

12. Heating is continued to 75-80°C and stearic acid is  
added. The composition is allowed to melt and disperse. Stearyl  
alcohol is added and then DC 3225C followed by DC 593, and  
mixed until uniform.

13. Dimethicone is added and all ingredients are well  
dispersed.

14. The composition is held at 75-80°C for phasing.

**Phasing**

20. 15. When the oil phase is at 75-80°C and the water  
phase is at 70-75°C, the oil phase (phase B) is added to the water  
phase (phase A) slowly while homogenizing for 5-10 minutes to  
ensure a homogeneous batch.

16. 25. Triethanolamine is slowly added and mixed for 10  
minutes or until a homogenous batch is achieved.

17. Homogenizer is turned off and the composition is  
mixed and cooled to 40-45°C.

18. 30. Salicylic acid is added to the premix

19. Fragrance is added and mixed for 20-25 minutes or  
until uniform.

20. Viscosity and pH measurement are taken at 25°C.

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The following example is inteded to illustrate the invention without being limiting in nature.

5           **EXAMPLE**

Component CTFA Name	Component Trade Name	% (w/w) q.s.
Water		
Carbomer	Carbbopol Ultrez 10 Polymer	0.30
Acrylates/ C <sub>10-30</sub> Alkyl Acrylate Crosspolymer	Pemulen TR-1	0.20
Disodium EDTA	Trilon BD	0.05
Glycerin	Pricerine 9073	3.0
Cyclomethicone (and)Dimethicone Copolyol	DC 3225C	2.0
Isohexadecane	Isohexadecane	2.0
Dimethicone (and) Trimethylsiloxy silicate	DC 593	2.0
Dimethicone	DC 200/350 cst	2.0
Stearyl Alcohol	Lanette 18	1.0
Stearic Acid	Prisetrine 4900	1.0
Cetyl Alcohol	Lanette 16	2.0
Phenoxyethanol & parabens	Phenonip	1.0
Propylene Glycol	Propylene Glycol USP	3.0
Salicylic Acid	Salicylic Acid	0.50
Butylated Hydroxy Toluene	BHT	0.02
Triethanolamine	Trolamine	1.38
Fragrance	ModTwist	0.5

**WHAT IS CLAIMED IS:**

1. An oil-free skin care composition for moisturizing the skin comprising:
  - (e) a humectant comprising glycerin and propylene glycol;
  - (f) an emollient comprising isohexadecane, cylcomethicone,  
5 dimethicone, dimethicone copolyol and trimethylsiloxy silicate;
  - (g) a keratolytic agent; and
  - (h) water.
2. The composition according to claim 1, comprising a stabilizing effective amount  
of an emulsifier.
- 10 3. The composition of claim 2, wherein the emulsifier is selected from stearic acid,  
cetyl alcohol and stearyl alcohol.
4. The composition of claim 1, comprising a stabilizing effective amount of a  
thickener.
- 15 5. The composition of claim 1, wherein the keratolytic agent is selected from  
salicylic acid.
6. The composition of claim 1, further comprising an effective amount of a  
preservative.
7. The composition of claim 1, further comprising an effective amount of a  
chelating agent.
- 20 8. The composition of claim 7 wherein the chelating agent is selected from the  
group consisting of ethylenediamine tetra acetic acid (EDTA) and salts thereof.
9. The composition of claim 1, further comprising an antioxidant.
10. The composition of claim 9, wherein the antioxidant is selected from butylated  
hydroxy toluene (BHT), ascorbyl palmitate, butylated hydroanisole (BHA),  
25 phenyl- $\alpha$ -naphthylamine, hydroquinone, propyl gallate, nordihydroquaiaretic acid,  
and mixtures thereof.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU 00/01067

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
Int Cl <sup>7</sup> : A61K 7/48; A61P 17/16		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) IPC A61K 7/48, A61K 7/40		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU: IPC as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DERWENT: skin, glycerin, propylene glycol, isohexadecane, CAS : dimethicone, cyclomethicone and related terms.		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5525344 A (WIVELL), 11 June 1996 Whole document	1-10
A	US 3818105 A (COPPERSMITH et al.) 18 June 1974 Whole document	1-10
<input type="checkbox"/> Further documents are listed in the continuation of Box C		<input checked="" type="checkbox"/> See patent family annex
<p>* Special categories of cited documents:</p> <p>"A" Document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&amp;" document member of the same patent family</p>		
Date of the actual completion of the international search 10 October 2000	Date of mailing of the international search report <b>25 OCT 2000</b>	
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No.: (02) 6285 3929	Authorized officer <b>STEVEN CHEW</b> Telephone No.: (02) 6283 2248	

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.  
PCT/AU 00/01067

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
US	5525344	CA	2164058	EP	722716	JP	8231336
		US	5525344				

END OF ANNEX